



Billing Code 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request
Information Collection Request Title: HRSA Ryan White HIV/AIDS Program AIDS Drug
Assistance Program Data Report, OMB No. 0915- 0345 – Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, pursuant to Section 3506(c)(2)(A), the Paperwork Reduction Act of 1995.

Information Collection Request Title: HRSA Ryan White HIV/AIDS Program (RWHAP) AIDS Drug Assistance Program Data Report, OMB No. 0915- 0345 – Revision

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) AIDS Drug Assistance Program (ADAP) is authorized under Part B of the RWHAP legislation, codified in sections 2611 et seq. of the Public Health Service Act, which provides grants to U.S. states and territories. RWHAP ADAP is a state and territory-administered program that provides Food and Drug Administration approved medications to low-income people with HIV who have limited or no health coverage from private insurance, Medicaid, or Medicare. RWHAP ADAP funds may also be used to purchase health insurance for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments.

All 50 states, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and the five U.S. Pacific Territories or Associated Jurisdictions receive RWHAP Part B grant awards including funds for RWHAP ADAP. RWHAP Part B reporting requirements include the annual submission of an ADAP Data Report (ADR), including a Recipient Report and a Client Report. The Recipient Report is a collection of basic information about grant recipient characteristics and policies including program administration, purchasing mechanisms, funding, and expenditures. The Client Report is a collection of client-level records (one record for each client enrolled in the RWHAP ADAP), which includes the client's encrypted unique identifier, basic demographic data, enrollment information, services received and clinical data.

HRSA is proposing several changes to the ADR Recipient and Client Reports to improve question clarity, delete obsolete data elements, combine related data elements, add new data elements, and improve response options to reflect program practices and support HRSA's analysis and understanding of program impact. Specifically, the Recipient Report includes the following proposed changes:

- addition of two new "Yes/No" questions,
- addition of one new follow-up question that requests the number of new clients enrolled,
- clarification on two existing questions,
- revision to one existing question that requests program income and manufacturer rebates reinvested in ADAP, and
- deletion of six obsolete data elements.

The Client Report includes the following proposed changes:

- revision to reporting of RWHAP ADAP-funded medications to include all medications rather than a subset of medications;
- revision to one existing question that requests reporting of all RWHAP ADAP-funded medications using the National Drug Code from the Drug Identification Code (d-codes);
- revision to reporting of clinical data for clients to include all clients rather than a subset of clients; and
- deletion of three data elements that were combined with other existing data elements.

Overall, HRSA does not anticipate these proposed revisions resulting in a change in the reporting burden. New and revised data elements require reporting of information that should already be collected by recipients to meet legislative or programmatic requirements for the proper oversight and administration of the program.

Need and Proposed Use of the Information: RWHAP requires the submission of annual reports by the Secretary of HHS to the appropriate committees of Congress. HRSA uses the ADR to evaluate the national impact of the RWHAP ADAP by providing client-level data on individuals being served, services being delivered, and costs associated with these services. The client-level data is used to monitor health outcomes of people with HIV receiving care and treatment through the RWHAP ADAP, to monitor the use of RWHAP ADAP funds in addressing the HIV epidemic and its impact on vulnerable communities, and to track progress toward achieving the goals identified in the National HIV/AIDS Strategy.

Likely Respondents: State ADAPs of RWHAP Part B recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hour

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Grantee Report	54	1	54	6	324
Client-level Report	54	1	54	81	4,374
Total	54*		54		4,698

*The same respondents complete the Grantee Report and the Client-level Report.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019-26099 Filed: 12/2/2019 8:45 am; Publication Date: 12/3/2019]